UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SHENG-PING ZHONG,
RONALD A. SAHATJIAN, and
ENXIN MA

Appeal No. 2006-2826
Application No. 09/993,907

ON BRIEF

Before GREEN, LINCK, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a medical device coated with a hydrogel polymer. The Examiner has rejected the claims as anticipated or obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm.

Background

The application relates to magnetic resonance imaging (MRI) of medical devices. MRI produces images by detecting protons in the object which is being imaged. Specification, ¶ 3. The object is placed in a powerful and uniform magnetic field. Id.

The protons in the area of interest align with the magnetic field. Id. Radiofrequency pulses are used to excite the aligned protons. Id. When they relax, a signal is produced which is measured by the MRI device and used to produce an image of the object. Id. The environment of the protons can affect the ability of MRI to detect and differentiate them from their surroundings. Id., ¶¶ 4, 24.

According to the specification, "[i]t is known to provide implantable or insertable medical devices with a coating on a surface of the device." Id., ¶ 21. The coatings can carry a therapeutic agent, provide a lubricious surface to facilitate introduction of the device into the patient, improve its biocompatibility, or other medical purposes. Id. MRI has been used to guide the insertion or implantation of medical devices. Id., ¶ 8. However, most polymers utilized to coat devices "do not produce adequate signals for detection by MRI techniques." Id. The application provides hydrogels which facilitate the visibility of medical devices upon placement into a patient. Id., ¶ 14.

Discussion

Claim construction

Claims 1, 3-8, 10-12, 15-38, and 69 are on appeal. Claims 39-41, 43, 44, and 46-68 are withdrawn from consideration pursuant to a requirement for restriction. Brief, page 2. There are eight prior art rejections; for each rejection, the claims stand or fall together because Appellants have not separately argued the patentability of any individual claim in the grouping. Claim 1 is the only independent claim on appeal which reads as follows:

1. An implantable or insertable medical device comprising:
(a) a substrate;
(b) a hydrogel polymer coating at least a portion of the surface of the substrate, wherein said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging upon insertion or implantation of said medical device into a patient, and wherein visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking.

We begin with claim construction because that is necessary to determine the scope and meaning of the claims. For this purpose, we will focus on claim 1 as representative. The claim is directed to a medical device which has a surface ("substrate") coated with a hydrogel. The hydrogel polymer which coats the substrate is required to be "adapted by cross-linking said hydrogel polymer to a degree sufficient to render" the device visible to MRI imaging. There is no definition in the specification of what is meant by "cross-linking." Accordingly, we adopt its ordinary and conventional meaning[1] that chains of atoms in the hydrogel polymer are joined together by bonds, atoms, or chemical groups.

The specification explains that cross-linking ("adapted by cross-linking") the hydrogel modifies its magnetic environment in comparison to the magnetic environment surrounding the coated device. Specification, ¶ 33. Coating a device with the cross-linked hydrogel facilitates the visibility of the device because "detectable species" associated with the hydrogel will behave differently than "detectable species" in the surroundings. Id., ¶¶ 24-26, 29. Claim 1's subsequent "wherein" clause indicates that the "detectable species" are "associated with" the hydrogel, and that their visibility "is

[1] Crosslink: "1. a bond, atom, or group linking the chains of atoms in a polymer, protein, or other complex organic molecule." The Random House College Dictionary, 319 (Rev. ed. 1982).

modified by varying the degree of cross-linking." In other words, the ability of the hydrogel-coated device to be "seen" by MRI is enabled by detection of the detectable species associated with the hydrogel. According to the specification, this works because the change in magnetic field may change the relaxation time of the detectable species, which is measurable by MRI. Id., ¶¶ 30, 87. As a consequence, the device is visualized ("render ... visible") in the resulting MRI image.

In MRI, the "detectable species" are typically protons that "behave like tiny magnets" in the magnetic field produced during MRI. Id., ¶ 3. The protons can be provided by water, hydroxylated molecules, or other chemical groups protons "associated with said hydrogel polymer." Id., ¶ 31, 32. The phrase "associated with" is defined in the specification to mean the chemical bonding which incorporates the detectable species in the hydrogel polymer. Id., ¶ 27.

There is no quantity of cross-linking recited in the claims, nor which is described in the specification. Moreover, claim 1 does not require the cross-linked hydrogel to have a specific structure. Consequently, we construe the phrase "adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible" to be a functional limitation, i.e., any cross-linked structure can meet the claimed limitation as long as it possesses the claimed "visibility" function.

Anticipation under § 102

DiCosmo

Claims 1, 3-5, 30, and 35 stand rejected under 35 U.S.C. § 102(b) as anticipated by DiCosmo.[2]

DiCosmo describes a medical device, such as a catheter or stent, which is coated with a hydrogel. DiCosmo, column 5, lines 40-64. The hydrogel ("matrix material)" is preferably a cross-linked material. Id., column 5, lines 64-67. We agree with the Examiner that these elements meet the structural limitations of claim 1, which requires a medical device having a substrate and a hydrogel polymer which is cross-linked.

The Examiner argued that the hydrogel would inherently possess the claimed functional limitation that its cross-linking be "sufficient to render said medical device visible" under MRI. Answer, page 3. Appellants challenged this conclusion, contending that the Examiner did not provide adequate evidence to show that the claimed feature would be an inherent property of the hydrogel disclosed by DiCosmo. Brief, pages 6-7.

As we have construed the claim, the limitation that the hydrogel cross-linking be "sufficient to render said medical device visible" under MRI is functional because it does not specify the structure of the hydrogel, nor the chemical nature and degree to which it is cross-linked. The court in In re Schreiber, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997) addressed the issue of a functional limitation that was alleged to distinguished the claimed subject matter over the prior art:

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[2] DiCosmo et al. (DiCosmo), U.S. Pat. No. 6,475,516, issued Nov. 5, 2002.

> A patent applicant is free to recite features of an apparatus either structurally or functionally. See In re Swinehart, 439 F.2d 210, 212, 169 USPQ 226, 228 (CCPA 1971) ("[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims."). Yet, choosing to define an element functionally, i.e., by what it does, carries with it a risk. As our predecessor court stated in Swinehart, 439 F.2d at 213, 169 USPQ at 228: where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

The Examiner's reason for asserting that DiCosmo's hydrogel covered device would render the device visible under MRI is that the hydrogel is cross-linked and thus has the same structure required by the claims. Thus, a "basis in fact and/or technical reasoning" was provided by the Examiner to support the rejection, contrary to Appellants' argument. Brief, page 7; Reply brief, page 3.

There is also no requirement in patent law that the cross-linking would have been recognized by the skilled artisan as having conferred visibility to the medical device as long as this property was nonetheless inherent to it. "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." MEHL/Biophile International Corp. v. Milgraum, 192 F.3d 1362, 1365, 52 USPQ2d 1303, 1305-6 (Fed. Cir. 1999).

Having shown that the claimed medical device has the same structure as DiCosmo's device, we find that the Examiner properly shifted the burden to Appellants to prove otherwise. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658; In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138-39 (Fed. Cir. 1986); In re Best, 562

F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1976). On this point, we see no discussion in the specification or Appellants' briefs addressing why DiCosmo's prior art hydrogel-covered device does not possess the required degree of cross-linking to make it visible to MRI. Furthermore, although the specification provides numerous examples of prior art hydrogels that are suitable for the claimed subject matter, Appellants do not explain what steps must be taken to adapt them to have the claimed MRI property. Specification, ¶¶ 28, 35. For example, the application characterizes the "cross-linked hydrogel polymers" disclosed in the Zhong patent as "useful in the present invention," but does not describe what, if any, steps are necessary to modify these admitted prior art polymers to make a medical device visible under MRI. Id., ¶35. Example 6 in the application shows the effect of cross-linking on proton relaxation times, but does not explain how the cross-linking procedure nor how the hydrogel, itself, differs from those disclosed in the prior art. Id., page 31.

In sum, we find that the Examiner has properly presumed the presence of the claimed limitation in DiCosmo, providing adequate evidence to establish prima facie anticipation. Since Appellants have not provided any evidence to contrary, we affirm this rejection.

Whitbourne

Claims 1, 3-7, 30, and 35 are rejected under 35 U.S.C. § 102(b) as anticipated by Whitbourne.[3]

Whitbourne describes a biomedical device coated with a hydrophilic polymer that

[3] Whitbourne, U.S. Pat. No. 5,331,027, issued Jul. 19, 1994.

swells in an aqueous environment to become a hydrogel. Whitbourne, column 1, lines 15-22, and 58-61; column 3, lines 52-63. In preferred embodiments, the polymer contains cross-linking. Id., column 4, lines 59-63. The device, substrate, and cross-linked polymer disclosed by Whitbourne were stated by the Examiner to meet the structural elements of claim 1. Answer, page 3. The Examiner found that, since the structural limitations were met, Whitbourne's coated device would reasonably be presumed to also possess the claimed properties that Appellants rely on for patentability. Id. We see no error in the Examiner's reasoning. Since Appellants have not rebutted this presumption by proving Whitbourne does not possess these properties, for the reasons discussed above, we affirm the rejection.

Weissleder

Claims 1, 3-5, 10, 11, 15-22, 28-31, and 35 stand rejected under 35 U.S.C. § 102(b) as anticipated by Weissleder.[4]

The Weissleder patent describes hydrogels for MRI imaging. Weissleder, column 3, lines 28-35. Also disclosed is the following method:

> a method for providing an image of an interventional device in an internal region of a patient in real time by coating the device with a labeled hydrogel, using the device in an internal region in the patient, and scanning the patient using an imaging technique that can detect the label to obtain an image of the device. The invention also covers interventional devices coated with a labeled hydrogel.

Id., column 5, lines 24-31

The hydrogels can be loaded with labels for MRI imaging, such as gadolinium containing compounds. Id., column 4, lines 1-8.

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[4] Weissleder et al. (Weissleder), U.S. Pat. No. 5,514,379, issued May 7, 1996.

The hydrogel and devices disclosed by Weissleder were stated by the Examiner to meet the structural limitations set forth in claim 1. Answer, pages 3-4. Because these limitations were met, the Examiner properly reasoned that the degree of hydrogel cross-linking was sufficient to cause it to be visible when under MRI.

Appellants challenged the rejection, arguing that Weissleder's purpose in cross-linking the hydrogel is "to ensure [its] insolubility" in order to load it with the magnetically active labels which are detectable by MRI." Brief, page 8, paragraphs 3-6. Once labeled, imaging of the hydrogel is achieved because of the presence of the label, not the hydrogel's degree of cross-linking. Id., page 9.

We are not persuaded by this argument. The fact that a paramagnetic label was used by Weissleder to visualize the device does not preclude the cross-linked gel from having been sufficient by itself to have made the device visible to MRI. Weissleder's purpose is not relevant to the question of whether the hydrogel-coated device would possess the claimed features, albeit unrecognized at the time.

For the reasons discussed previously, we conclude that the Examiner has provided sufficient evidence to establish a case of prima facie anticipation, which Appellants have not overcome. This rejection is affirmed.

Obviousness under § 103

Weissleder in view of Michaels

Claims 6-8 are rejected under 35 U.S.C. § 103(a) as rendered obvious over Weissleder in view of Michaels[5].

Michaels teaches laminate membrane structures that contain hydrogels. Michaels, column 2, lines 57-60. The hydrogel layers can be treated with glycerin to protect them from cracking when the membrane is dried. Id., column 16, lines 50-59. The Examiner argued that it would have been obvious to have applied glycerin to Weissleder's hydrogel to prevent cracking when applied to the medical device's substrate. Answer, page 4.

Appellants argued that "Michaels discloses glycerin only as a plasticizer, and its disclosure would add nothing relevant to the disclosure of Weissleder ..., especially since no suggestion or motivation to combine the reference teachings can be found in the references." Brief, page 10.

Obviousness does not require an express suggestion to modify the prior art. In re Kahn, 441 F.3d 977, 987-988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). The Examiner provided a reasoned statement explaining why the skilled worker would have utilized glycerin in a hydrogel. Answer, page 4. We concur with the Examiner that it would have been reasonable at the time the invention was made for the skilled worker to have utilized glycerin in Weissleder's hydrogel for its advantages as taught by Michaels. Appellants have not identified a defect in this reasoning. Accordingly, we affirm this rejection.

Weissleder in view of Klaveness

Claim 12 stands rejected under 35 U.S.C. § 103(a) as rendered obvious over Weissleder in view of Klaveness.[6]

The Examiner cited Klaveness for its teaching of paramagnetic particles comprising starch-coated ion oxide particles. Answer, page 4. Appellants acknowledged that these particles were known in the prior art. Brief, page 10. No additional arguments were provided except to the extent to state that Klaveness "adds nothing relevant to Weissleder." Id. For the reasons stated by the Examiner, we find that sufficient evidence of prima facie obviousness has been established. Thus, we affirm this rejection.

Weissleder in view of Peng

Claim 23 stands rejected under 35 U.S.C. § 103(a) as rendered obvious over Weissleder in view of Peng.[7]

Peng teaches chelating groups that comprise aminopolycarboxylic acid as recited in claim 23. Answer, page 5. The Examiner concluded:

> It would have been obvious to one skilled in the art to have modified Weissleder et al such that it includes aminopolycarboxylic acid as the chelating agent for use with paramagnetic particles. Such a modification merely involves the substitution of one well known type of chelating agent for another.

Id. at 5.

Appellants argued that the combination of references is "questionable" because Peng discloses pharmaceutical compositions, not coated medical devices. Brief,

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[5] Michaels, U.S. Pat. No. 6,112,908, issued Sep. 5, 2000.
[6] Klaveness et al. (Klaveness), U.S. Pat. No. 6,610,269, issued Aug. 26, 2003.
[7] Peng et al. (Peng), U.S. Pub. Pat. App. No. 2002/0061871 A1, published May 23, 2002.

sentence spanning pages 10-11. This argument is not persuasive. Peng clearly characterizes aminopolycarboxylic acid chelating agents as useful for the chelation of paramagnetic metal ions in magnetic resonance imaging. Peng, ¶ 50. This is the same purpose recited in the claims. Thus, we do not see merit in Appellants' argument. Accordingly, we find that the Examiner has provided adequate evidence to estsblish prima facie obviousness. This rejection is affirmed.

Weissleder in view of Cleary

Claims 24-27, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as rendered obvious over Weissleder in view of Cleary.[8]

According to the Examiner, Weissleder discloses a hydrogel-coated medical device, but not a hydrogel that contains substituted or unsubstituted acrylic acid monomers or copolymers of acrylic acid and acrylamide units as required by the claims. Answer, page 5. This deficiency, the Examiner stated, is remedied by Cleary who teaches these polymers. Cleary, ¶¶ 13, 14, 68. The Examiner concluded that utilizing Cleary's polymers in Weissleder would have been obvious been "[s]uch a modification merely involves the substitution of one known type of hydrogel composition for another." Answer, page 5.

Appellants maintained that the rejection was improper because Cleary disclosed the polymers as useful for medical dressings, not coated medical devices as claimed. Brief, page 11. They urged that the Examiner did not explain where the suggestion and motivation to combine the references "could be found in the references themselves." Id.

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[8] Cleary et al. (Cleary), U.S. Pub. Pat. App. No. 2003/0170308 A1, published Sept. 11, 2003.

The teaching, suggestion or motivation to combine the references does not have to be explicitly disclosed in the prior art cited against the claimed subject matter. "[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." Kahn, 441 F.3d at 987-988, 78 USPQ2d at 1336.

The Examiner stated that it would have been obvious to have utilized Cleary's hydrogel polymer as the coating for a medical device for its properties as biocompatible polymer. Appellants admitted in the specification that medical devices coated with hydrogel's were known in the art prior to the application's filing date. Specification, ¶ 21. The scope and content of the prior art (Weissleder, but also DiCosmo and Whitbourne) would have reasonably suggested to the skilled worker that any biocompatible polymer could be utilized to coat a medical device, including the polymer described by Cleary. It does not change our mind that Cleary teaches the polymer for medical dressings, while the claimed subject matter is directed to medical devices. A skilled worker would have been charged with knowledge of its chemical properties since both are in the medical field. In re Dillon, 919 F.2d 688, 694 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (en banc).

Weissleder

Claims 34, 36-38, and 69 are rejected under 35 U.S.C. § 103(a) as rendered obvious over Weissleder.

On page 6 of the Answer, the Examiner set forth the grounds of the rejection. Appellants objected to it for the same reasons given for the claims rejected as anticipated by Weissleder:

> The rejection of these claims for obviousness, as did the rejection for anticipation, relies on an assertion of inherency supported only by unfounded speculation. That issue has been discussed at length above. The above discussed constraints on assertions of inherency apply to obviousness rejections as well as rejections for anticipation.

Brief, pages 11-12.

Appellants also stated that there was no "support in the references and/or clear and convincing explanation based on sound scientific reasoning" upon which the obviousness rejection was based. Id., page 12.

However, we find that the Examiner did explain his rationale for the rejection. Since we find no flaw in his reasoning, we affirm the rejection for the reasons provided in our analysis of the rejection over Weissleder under § 102.

Summary

The rejections of 1, 3-8, 10-12, 15-38, and 69 over prior art are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Lora M. Green)
Administrative Patent Judge)
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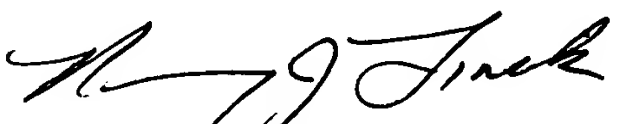
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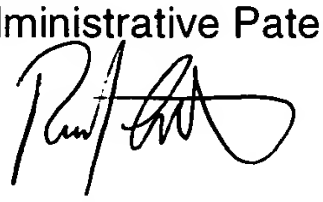
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Richard M. Lebovitz)
Administrative Patent Judge)

RL/dm

Mayer & Williams PC
251 North Avenue West
2nd Floor
Westfield, NJ 07090